

Claims:

1. A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:

5 (a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more isolated antigens from a first region of the HCV polyprotein;

(b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one
10 or more HCV antigens;

(c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV multiple epitope fusion antigen (MEFA), wherein said labeled MEFA comprises at least one epitope from the same region of the HCV polyprotein as the one or more isolated antigens, wherein said MEFA binds said bound HCV antibody;

15 (d) detecting complexes formed between said HCV antibody and said one or more antigens from the first region of the HCV polyprotein and said MEFA, if any, as an indication of HCV infection in the biological sample.

2. The method of claim 1, wherein the one or more isolated antigens from the
20 first region of the HCV polyprotein are one or more isolated NS3/4a conformational epitopes and the MEFA comprises at least one epitope from the NS3/4a region.

3. A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:

25 (a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more isolated HCV NS3/4a conformational epitopes;

(b) combining a biological sample with said solid support under conditions

which allow HCV antibodies, when present in the biological sample, to bind to said one or more NS3/4a epitopes;

(c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV multiple epitope fusion antigen (MEFA), wherein said labeled
5 MEFA comprises at least one epitope from the HCV NS3/4a region, wherein said MEFA binds said bound HCV antibody;

(d) detecting complexes formed between said HCV antibody and said NS3/4a conformational epitope and said MEFA, if any, as an indication of HCV infection in the biological sample.

10

4. The method of claim 3, wherein said NS3/4a conformational epitope comprises an epitope from the NS3/4a protease region of the HCV polyprotein.

5. The method of claim 3, wherein said NS3/4a conformational epitope
15 comprises an epitope from the NS3/4a helicase region of the HCV polyprotein.

6. The method of claim 3, wherein said NS3/4a conformational epitope comprises the amino acid sequence depicted in Figures 3A-3D (SEQ ID NO:2).

20 7. The method of claim 3, wherein said MEFA comprises an epitope from the NS3/4a protease region of the HCV polyprotein.

8. The method of claim 3, wherein said MEFA comprises an epitope from the NS3/4a helicase region of the HCV polyprotein.

25

9. The method of claim 8, wherein said MEFA comprises amino acids 1193-1657, numbered relative to the HCV-1 sequence.

10. The method of claim 3, wherein said MEFA comprises an epitope from the c33c region of the HCV polyprotein.

11. The method of claim 10, wherein said MEFA comprises amino acids 1211-
5 1457, numbered relative to HCV-1.

12. The method of claim 10, wherein said MEFA comprises amino acids 1192-
1457, numbered relative to HCV-1.

10 13. The method of claim 3, wherein said MEFA comprises an epitope from the 5-1-1 region of the HCV polyprotein.

14. The method of claim 13, wherein said MEFA comprises amino acids 1689-
1735, numbered relative to HCV-1.

15 15. The method of claim 3, wherein said MEFA comprises the amino acid sequence depicted in Figures 6A-6F (SEQ ID NO:4).

16. The method of claim 3, wherein said MEFA comprises the amino acid
20 sequence depicted in Figures 8A-8F (SEQ ID NO:6).

17. A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:

(a) providing an immunoassay solid support comprising HCV antigens bound
25 thereto, wherein the HCV antigens consist of one or more multiple epitope fusion antigens (MEFAs);

(b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one

or more MEFAs;

(c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled isolated HCV antigen from a region of the HCV polyprotein present in the one or more MEFAs, wherein said isolated antigen binds said bound HCV

5 antibody;

(d) detecting complexes formed between said HCV antibody and said isolated HCV antigen and said MEFA, if any, as an indication of HCV infection in the biological sample.

10 18. The method of claim 17, wherein the isolated HCV antigen is an isolated NS3/4a conformational epitope and the MEFA comprises at least one epitope from the NS3/4a region.

15 19. A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:

(a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more multiple epitope fusion antigens (MEFAs) wherein said one or more MEFAs comprise at least one epitope from the HCV NS3/4a region;

20 (b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one or more MEFAs;

(c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV NS3/4a conformational epitope, wherein said NS3/4a

25 conformational epitope binds said bound HCV antibody;

(d) detecting complexes formed between said HCV antibody and said NS3/4a conformational epitope and said MEFA, if any, as an indication of HCV infection in the biological sample.

20. The method of claim 19, wherein said NS3/4a conformational epitope comprises an epitope from the NS3/4a protease region of the HCV polyprotein.

5 21. The method of claim 19, wherein said NS3/4a conformational epitope comprises an epitope from the NS3/4a helicase region of the HCV polyprotein.

22. The method of claim 19, wherein said NS3/4a conformational epitope comprises the amino acid sequence depicted in Figures 3A-3D (SEQ ID NO:2).

10

23. The method of claim 19, wherein said MEFA comprises an epitope from the NS3/4a protease region of the HCV polyprotein.

24. The method of claim 19, wherein said MEFA comprises an epitope from the
15 NS3/4a helicase region of the HCV polyprotein.

25. The method of claim 24, wherein said MEFA comprises amino acids 1193-1657, numbered relative to the HCV-1 sequence.

20 26. The method of claim 19, wherein said MEFA comprises an epitope from the c33c region of the HCV polyprotein.

27. The method of claim 26, wherein said MEFA comprises amino acids 1211-1457, numbered relative to HCV-1.

25

28. The method of claim 26, wherein said MEFA comprises amino acids 1192-1457, numbered relative to HCV-1.

29. The method of claim 19, wherein said MEFA comprises an epitope from the 5-1-1 region of the HCV polyprotein.

30. The method of claim 29, wherein said MEFA comprises amino acids 1689-
5 1735, numbered relative to HCV-1.

31. The method of claim 19, wherein said MEFA comprises the amino acid sequence depicted in Figures 6A-6F (SEQ ID NO:4).

10 32. The method of claim 19, wherein said MEFA comprises the amino acid sequence depicted in Figures 8A-8F (SEQ ID NO:6).